

**IN THE UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF TEXAS  
DALLAS DIVISION**

**CAROLYN CARPENTER,**

Plaintiff,

v.

**BOSTON SCIENTIFIC  
CORPORATION,**

Defendant.

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Civil Action No. **3:18-CV-02338-L**

**MEMORANDUM OPINION AND ORDER**

Before the court are Defendant Boston Scientific Corporation’s (“Defendant” or “Boston Scientific”) Motion to Dismiss for Failure to State a Claim (Doc. 5), filed September 11, 2018; Plaintiff Carolyn Carpenter’s (“Plaintiff” or “Carpenter”) Response (Doc. 10), filed October 2, 2018; and Defendant’s Reply (Doc. 11), filed October 16, 2018.

After careful consideration of the motion, briefs, pleadings, and applicable law, the court **grants** Defendant’s Motion to Dismiss for Failure to State a Claim (Doc. 5); **dismisses with prejudice** Plaintiff’s breach of implied and express warranty claims as being barred by the statute of limitations; and **dismisses without prejudice** Plaintiff’s negligence and strict liability claims but allows her to file an amended pleading.

**I. Factual and Procedural Background**

On July 27, 2018, Carpenter filed Plaintiff’s Original Petition (the “Petition”) in the 68th Judicial District Court of Dallas County, Texas, asserting the following state law claims against Boston Scientific: (1) negligence; (2) strict liability for a design defect; (3) strict liability for a manufacturing defect; (4) strict liability for failure to warn; (5) breach of implied warranty; and

(6) breach of express warranty. Def.’s Notice of Removal, Doc. 1 at 1; Pl.’s Pet., Doc. 1-3 at 11-15. Boston Scientific was served on August 13, 2018, and removed this action to federal court on September 4, 2018, on the basis of diversity jurisdiction. Def.’s Notice of Removal, Doc. 1 at 1-3; Ex. B., Doc. 1-2 at 3.

Carpenter asserts that these claims arise based on her being surgically implanted with Boston Scientific’s medical device, the Advantage Fit Transvaginal Mid-Urethral Sling System (the “Advantage Fit”). The Advantage Fit is a device composed of polypropylene mesh that is implanted onto a woman’s vaginal wall and secured in place by two arms that extend through the pelvis. Pl.’s Pet., Doc. 1-3, ¶ 7. The purpose of the device is to correct and restore the normal vaginal structure of women who suffer from pain, discomfort, and urinary incontinence. *Id.*

On April 5, 2012, Carpenter underwent surgery at Texas Health Presbyterian Hospital Plano and was implanted with the Advantage Fit to treat her urinary incontinence. Pl.’s Pet., Doc. 1-3, ¶ 32. Carpenter alleges that, as a result of the implantation of the device, she suffered complications that required corrective surgeries. Specifically, she contends that, in January 2017, she had surgery to remove stones from her bladder; in May 2017, she had surgery to remove mesh that had eroded into her bladder; and in May 2018, she had surgery to remove additional mesh that had eroded into her bladder and treat bladder lesions. Pl.’s Pet., Doc. 1-3, ¶¶ 33-35. Carpenter alleges that she will continue to suffer injury as a result of being implanted with the Advantage Fit device, including pain, discomfort, chronic infections, surgeries, and erosion of the device into her surrounding organs and tissues. Pl.’s Pet., Doc. 1-3, ¶ 36.

Carpenter asserts that scientific evidence shows that “this material is biologically incompatible with human tissue and promotes an immune response,” which causes the mesh material to degrade, leading to “the formation of severe adverse reactions.” Pl.’s Pet., Doc. 1-3, ¶

9. Carpenter asserts that Boston Scientific, in promoting the Advantage Fit, has made exaggerated and misleading representations regarding the safety, utility, and efficacy of the device. Pl.’s Pet., Doc. 1-3, ¶ 11. Carpenter asserts that, in addition to her, a significant number of women who were implanted with the Advantage Fit have subsequently experienced severe and irreversible injuries as a result of the device and have required frequent and often debilitating revision surgeries. Pl.’s Pet., Doc. 1-3, ¶ 12. Some of the resulting injuries, she contends, include: mesh erosion, infection, inflammation, scar tissue, organ perforation, blood loss, acute and chronic nerve damage and pain, and urinary and fecal incontinence. Pl.’s Pet., Doc. 1-3, ¶ 26. Carpenter contends that the medical and scientific literature studying the effects of polypropylene mesh, the material used in the Advantage Fit, has concluded that “each of these injuries, conditions, and complications . . . are in fact causally related to the mesh itself and do not often implicate errors related to the implantation of the devices.” Pl.’s Pet., Doc. 1-3, ¶ 27. Carpenter contends that the FDA issued warnings in 2008 and 2011, regarding the use of transvaginal mesh products. Pl.’s Pet., Doc. 1-3, ¶ 7.

On September 11, 2018, Boston Scientific filed its Motion to Dismiss. Boston Scientific argues that Carpenter’s claims are barred by the applicable statutes of limitations, that her Petition fails to state a claim upon which relief can be granted, and that it should be dismissed pursuant to Federal Rule of Civil Procedure 12(b)(6) (“Rule 12(b)(6)”). For the reasons that follow, the court determines that Carpenter’s breach of implied and express warranty claims are barred by the statute of limitations; that the pleadings do not support Defendant’s arguments that her negligence and strict liability claims are time-barred; and that, although the Petition has factual deficiencies with respect to the negligence and strict liability claims, Carpenter will be permitted to replead her claims in an amended complaint.

## **II. Rule 12(b)(6) – Failure to State a Claim**

To defeat a motion to dismiss filed pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, a plaintiff must plead “enough facts to state a claim to relief that is plausible on its face.” *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007); *Reliable Consultants, Inc. v. Earle*, 517 F.3d 738, 742 (5th Cir. 2008); *Guidry v. American Pub. Life Ins. Co.*, 512 F.3d 177, 180 (5th Cir. 2007). A claim meets the plausibility test “when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. The plausibility standard is not akin to a ‘probability requirement,’ but it asks for more than a sheer possibility that a defendant has acted unlawfully.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (internal citations omitted). While a complaint need not contain detailed factual allegations, it must set forth “more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” *Twombly*, 550 U.S. at 555 (citation omitted). The “[f]actual allegations of [a complaint] must be enough to raise a right to relief above the speculative level . . . on the assumption that all the allegations in the complaint are true (even if doubtful in fact).” *Id.* (quotation marks, citations, and footnote omitted). When the allegations of the pleading do not allow the court to infer more than the mere possibility of wrongdoing, they fall short of showing that the pleader is entitled to relief. *Iqbal*, 556 U.S. at 679.

In reviewing a Rule 12(b)(6) motion, the court must accept all well-pleaded facts in the complaint as true and view them in the light most favorable to the plaintiff. *Sonnier v. State Farm Mutual Auto. Ins. Co.*, 509 F.3d 673, 675 (5th Cir. 2007); *Martin K. Eby Constr. Co. v. Dallas Area Rapid Transit*, 369 F.3d 464, 467 (5th Cir. 2004); *Baker v. Putnal*, 75 F.3d 190, 196 (5th Cir. 1996). In ruling on such a motion, the court cannot look beyond the pleadings. *Id.*; *Spivey v. Robertson*, 197 F.3d 772, 774 (5th Cir. 1999). The pleadings include the complaint and any

documents attached to it. *Collins v. Morgan Stanley Dean Witter*, 224 F.3d 496, 498-99 (5th Cir. 2000). Likewise, “[d]ocuments that a defendant attaches to a motion to dismiss are considered part of the pleadings if they are referred to in the plaintiff’s complaint and are central to [the plaintiff’s] claims.” *Id.* (quoting *Venture Assocs. Corp. v. Zenith Data Sys. Corp.*, 987 F.2d 429, 431 (7th Cir. 1993)). In this regard, a document that is part of the record but not referred to in a plaintiff’s complaint and not attached to a motion to dismiss may not be considered by the court in ruling on a 12(b)(6) motion. *Gines v. D.R. Horton, Inc.*, 699 F.3d 812, 820 & n.9 (5th Cir. 2012) (citation omitted).

The ultimate question in a Rule 12(b)(6) motion is whether the complaint states a valid claim when it is viewed in the light most favorable to the plaintiff. *Great Plains Trust Co. v. Morgan Stanley Dean Witter*, 313 F.3d 305, 312 (5th Cir. 2002). While well-pleaded facts of a complaint are to be accepted as true, legal conclusions are not “entitled to the assumption of truth.” *Iqbal*, 556 U.S. at 679 (citation omitted). Further, a court is not to strain to find inferences favorable to the plaintiff and is not to accept conclusory allegations, unwarranted deductions, or legal conclusions. *R2 Invs. LDC v. Phillips*, 401 F.3d 638, 642 (5th Cir. 2005) (citations omitted). The court does not evaluate the plaintiff’s likelihood of success; instead, it only determines whether the plaintiff has pleaded a legally cognizable claim. *United States ex rel. Riley v. St. Luke’s Episcopal Hosp.*, 355 F.3d 370, 376 (5th Cir. 2004). Stated another way, when a court deals with a Rule 12(b)(6) motion, its task is to test the sufficiency of the allegations contained in the pleadings to determine whether they are adequate enough to state a claim upon which relief can be granted. *Mann v. Adams Realty Co.*, 556 F.2d 288, 293 (5th Cir. 1977); *Doe v. Hillsboro Indep. Sch. Dist.*, 81 F.3d 1395, 1401 (5th Cir. 1996), *rev’d on other grounds*, 113 F.3d 1412 (5th Cir. 1997) (en banc). Accordingly, denial of a 12(b)(6) motion has no bearing on whether a plaintiff

ultimately establishes the necessary proof to prevail on a claim that withstands a 12(b)(6) challenge. *Adams*, 556 F.2d at 293.

A statute of limitations may support dismissal pursuant to Rule 12(b)(6) when it is evident from a plaintiff's pleadings that the action is time-barred and the pleadings fail to set forth or raise some basis for tolling the statute. *Jones v. Alcoa, Inc.*, 339 F.3d 359, 366 (5th Cir. 2003) (citations omitted).

### **III. Analysis**

#### **A. Statute of Limitations**

##### **1. Plaintiff's Breach of Implied and Express Warranty Claims**

Defendant argues that Plaintiff's breach of implied and express warranty claims are barred by the applicable four-year statute of limitations, as set forth in § 2.725 of the Texas Business and Commerce Code. Def.'s Mot. to Dismiss, Doc. 6 at 3. Defendant argues that warranty claims accrue on the date of delivery of the product, which was, at the latest, April 5, 2012, when Plaintiff alleges she was implanted with the Advantage Fit. *Id.* Defendant contends that, in light of the four-year statute of limitations, her claims expired in April 2016, and, as she did not file this lawsuit until 2018, her breach of implied and express warranty claims are time-barred and should be dismissed.

In response, Plaintiff concedes that her warranty claims are time-barred. In so doing, she does not set forth any reason why the applicable four-year statute of limitations should be tolled with respect to these claims. Pl.'s Resp., Doc. 10 at 1. The court, accordingly, **grants** Defendant's motion to dismiss with respect to its argument that Plaintiff's breach of warranty claims are time-barred and **dismisses with prejudice** Plaintiff's claims for breach of express and implied warranties.

## **2. Plaintiff's Negligence and Strict Liability Claims**

Defendant argues that Plaintiff's negligence and strict liability claims should be dismissed as barred by the two-year statute of limitations applicable to personal injury claims, as set forth in § 16.003 of the Texas Civil Practice and Remedies Code. Def.'s Mot. to Dismiss, Doc. 6 at 2. Defendant argues that, under Texas law, negligence actions begin to accrue the moment a wrongful act causes injury, regardless of when the plaintiff identifies the injury. *Id.* (citing *Childs v. Haussecker*, 974 S.W.2d 31, 36 (Tex. 1998)). Defendant argues that the allegedly wrongful act in this case is the implantation of the Advantage Fit device on April 5, 2012, and, therefore, any personal injury claims arising from that act expired in April 2014. *Id.* at 2-3.

Defendant argues that Plaintiff is not entitled to the "discovery rule" exception that, under Texas law, determines that a personal injury claim accrues when the plaintiff discovers or in the exercise of reasonable diligence should have discovered the wrongful act and resulting injury, particularly when it is otherwise difficult for the injured party to learn of the act. Def.'s Mot. to Dismiss, Doc. 6 at 2 n.2.; Def.'s Reply, Doc. 11 at 2-4; *see S.V. v. R.V.*, 933 S.W.2d 1, 4, 6 (Tex. 1996). Defendant first argues that Plaintiff failed to affirmatively plead the discovery rule in her Petition, which is required under Texas procedural law. Def.'s Mot. to Dismiss, Doc. 6 at 2 n.2 (citing *Woods v. William M. Mercer, Inc.*, 769 S.W.2d 515 (Tex. 1988)). Second, Defendant argues that Plaintiff's Response fails to demonstrate that the discovery rule is applicable in this case, as she "fails to allege the date on which she claims to have discovered her own injuries" and, "[w]ithout these important dates, Plaintiff's pleadings fail to raise a basis to toll the statute of limitations." Def.'s Reply, Doc. 11 at 3. Defendant argues that, at most, Plaintiff has asserted that the FDA publicly issued various notices in 2008 and 2011 regarding the risks and dangers of mesh products such as the Advantage Fit and that Plaintiff asserts that in 2012, the Judicial Panel on

Multi District Litigation issued an order consolidating cases against Defendant involving the transvaginal mesh products, in which over 25,704 cases have since been consolidated. Def.'s Reply, Doc. 11 at 3 (citing Pl.'s Resp., Doc 10 at 2). Defendant argues that Plaintiff, in acknowledging these public notices in 2008, 2011, and 2012, regarding the hazards allegedly posed by the Advantage Fit, pleads herself out of the ability to argue that the discovery rule should apply based on an accrual date any later than, at most, 2012. *Id.* at 3-4.

With respect to Defendant's argument that Plaintiff was required to plead specifically the discovery rule in her petition, Plaintiff correctly argues that, in federal court, this requirement does not apply. Pl.'s Resp., Doc. 10 at 4 (citing *Wellborn v. Sears, Roebuck & Co.*, 970 F.2d 1420, 1425 (5th Cir. 1992) (holding that the pleading standard set forth in *Woods*, 769 S.W.2d at 518, does not apply in federal court)). Plaintiff argues that she has pleaded sufficient facts to demonstrate that the discovery rule applies, specifically facts alleging that "Defendant repeatedly and continuously hid the risk and dangers of its Advantage Fit product from the Plaintiff, her physician, the public, and the FDA [Food and Drug Administration]." Pl.'s Pet., Doc. 10 at 5. Carpenter argues that her claims "could not have accrued upon implant as Defendant continued to suppress and failed to disseminate accurate information about the dangers of the Advantage Fit or the injuries it could cause to Plaintiff and her physician." *Id.* She does not set forth an accrual date for the court to consider that is also supported by the pleadings; she argues, rather, that "when Plaintiff's claims began to accrue is a question of fact not appropriate for dismissal at this juncture." *Id.*

As previously stated in the court's standard for reviewing a Rule 12(b)(6) motion, a statute of limitations may support dismissal pursuant to Rule 12(b)(6) when it is evident from a plaintiff's pleadings that the action is time-barred, and the pleadings fail to set forth or raise some basis for



tolling the statute. *Jones*, 339 F.3d at 366. For the following reasons, the court determines that the pleadings adequately set forth factual bases for applying the discovery rule and tolling the statute.

The discovery rule is “a very limited exception to statutes of limitations.” *Shell Oil Co. v. Ross*, 356 S.W.3d 924, 929 (Tex. 2011) (citation omitted). It applies when the nature of the plaintiff’s injury is “inherently undiscoverable and the evidence of injury is objectively verifiable.” *BP Am. Prod. Co. v. Marshall*, 342 S.W.3d 59, 65-66 (Tex. 2011) (citation omitted). The discovery rule “serves to defer the accrual of a cause of action until the plaintiff knew, or exercising reasonable diligence, should have known of the facts giving rise to the claim.” *Gale v. Lucio*, 445 S.W.3d 849, 857 (Tex. App.—Houston [1st Dist.] 2014, pet. denied).

As the party asserting a statute of limitations defense, Boston Scientific must negate the discovery rule as a matter of law. *Schouest v. Medtronic, Inc.*, 13 F. Supp. 3d 692, 708 (S.D. Tex. 2014) (citations omitted). “When an evidentiary record can be considered, the statute of limitations may prove a successful defense, but at the Rule 12 stage, it is insufficient to warrant dismissal” when a plaintiff alleges that the discovery rule tolled his or her claims until some point within the statute of limitations. *Id.* The court determines that Plaintiff’s pleadings set forth sufficient allegations to support the discovery rule exception and that Defendant failed to negate the rule. Carpenter contends that, in January 2017, she underwent her first corrective surgery “[a]s a result of the implantation of the Advantage Fit” to remove stones from her bladder.” Pl.’s Pet., Doc. 1-3 at 10, ¶ 33. She contends that she underwent an additional two corrective surgeries “[a]s a result of the implantation of the Advantage Fit” in May 2017, to remove mesh that had “eroded into her bladder,” and May 2018, to remove additional mesh which had also “eroded into her bladder” and to treat bladder lesions. *Id.* at 11, ¶¶ 34-35. While Defendant raises the point that public notices were issued, through FDA warnings in 2008 and 2011 and the consolidation of lawsuits against

Boston Scientific in 2012, it has not sufficiently persuaded the court that Plaintiff, with reasonable diligence, should have discovered these notices.

As neither party provided the court with any legal authority, the court conducted its own research to address this issue. The Texas Supreme Court recently noted that it has “held that the discovery rule applies in certain circumstances even though the injury could have been gleaned from reviewing publicly available information.” *Archer v. Tregellas*, 566 S.W.3d 381, 390-92 (Tex. 2018). The court cited *Kelly v. Rinkle*, in which it applied the discovery rule to a libel action based on the submission of a false credit report to a reporting agency, explaining that a “person will not ordinarily have any reason to suspect that he [or she] has been defamed by the publication of a false credit report to a credit agency until he [or she] makes application for credit to a concern which avails itself of the information furnished by the credit agency.” *Id.* (quoting 532 S.W.2d 947, 949 (Tex. 1976)).

In other circumstances, courts decline to apply the discovery rule when the parties fail to investigate readily accessible and publicly available information that would have revealed the nature of his or her injury. For example, in disputes regarding a plaintiff’s property interest, “[r]easonable diligence requires that owners of property interests make themselves aware of relevant information available in the public record,” such as by investigating public records of case settlements and conveyances. *Shell Oil Co. v. Ross*, 356 S.W.3d 924, 928 (Tex. 2011) (citing *Kerlin v. Saucedo*, 263 S.W.3d 920, 926 (Tex. 2008)); see also *HECI Exploration Co. v. Neel*, 982 S.W.2d 881, 887 (Tex. 1998). In the context of breach of contract claims, the Texas Supreme Court has stated that the application of the discovery rule “should be rare, as diligent contracting parties should generally discover any breach” during the limitations period. *Via Net v. TIG Ins. Co.*, 211 S.W.3d 310, 315 (Tex. 2006). In a claim involving a dispute over a business transaction between

“sophisticated” parties, reasonable diligence requires the parties to “acquaint themselves” with readily accessible, publicly available records. *Hooks v. Samson Lone Star, Limited Partnership*, 457 S.W.3d 52, 57 (Tex. 2015).

The court has not found Texas authority in which a plaintiff’s negligence and strict liability claims, based on injuries resulting from a medical device, were time-barred because he or she failed to reasonably investigate publicly available information of the kind alleged here, namely, FDA notices and an order by the Judicial Panel on Multi District Litigation consolidating cases against Defendant relating to the medical device at issue. Defendant has not provided any factually-analogous authority in support of its position that these public notices render the discovery rule inapplicable as a matter of law; therefore, the court does not believe this determination is proper at this early stage of the proceedings, without an adequate evidentiary record and additional briefing by the parties on this issue.

There are no allegations in the Petition that Carpenter was aware of the notices at the time they were issued in 2008, 2011, and 2012. Moreover, the pleadings do not set forth allegations that Plaintiff suffered injuries at any time between 2008 and 2011 that might have put her on notice that she was experiencing symptoms consistent with the hazards raised by these public notices. Plaintiff’s pleadings, rather, set forth factual allegations that she had surgeries in 2017 and 2018 to remove stones from her bladder and to remove mesh from the Advantage Fit device that had eroded in her bladder, surgeries that she allege resulted from the implantation of the device. As stated earlier, whether Carpenter should have discovered the existence of these public warnings through a diligent investigation is a question of fact that is more appropriately resolved at the summary judgment stage.

Based on the state of the record, the allegations set forth in the Petition support a reasonable inference that Carpenter had not discovered that Advantage Fit caused her injuries until she underwent the corrective surgeries. In the absence of a more fully developed evidentiary record, the court is unwilling to dismiss Plaintiff's claims based on a statute of limitations defense, when the pleadings set forth sufficient allegations to support tolling based on the discovery rule. Accordingly, the court **denies** Boston Scientific's motion to dismiss with respect to its argument that Carpenter's negligence and strict liability claims should be dismissed as time-barred.

## **B. Negligence and Strict Liability Claims**

### **1. Negligence Claim**

Under Texas law, to prevail on a negligence cause of action, a plaintiff must establish: (1) "the existence of a duty," (2) "a breach of that duty," and (3) "damages proximately caused by the breach." *Western Investments, Inc. v. Urena*, 162 S.W.3d 547, 550 (Tex. 2005) (citing *Doe v. Boys Clubs of Greater Dallas, Inc.*, 907 S.W.2d 472, 477 (Tex. 1995)).

Boston Scientific argues that Carpenter has failed to set forth sufficiently allegations to support her negligence claim because she failed to "identify any conduct by Boston Scientific that breached this standard of care, or identify the manner in which Boston Scientific's alleged breach proximately caused Plaintiff's injuries." Def.'s Mot. to Dismiss, Doc. 6 at 5. The court agrees. Carpenter's negligence claim, as set forth in the Petition, is wholly conclusory and contains no factual allegations to establish, or from which the court can reasonably infer, the three elements for a negligence cause of action. Carpenter's response to Boston Scientific's motion is likewise conclusory, arguing that she has "pled sufficient facts that correlate with her strict liability claim to satisfy the requirements for a negligence claim," without alleging with specificity to which facts

she refers. Pl.’s Resp., Doc. 10 at 8-9. The court, accordingly, determines that the Petition fails to meet the pleading standard with respect to Carpenter’s negligence claim.

## **2. Strict Liability – Design Defect Claim**

“To recover on a products liability claim arising out of a design defect, the plaintiff must prove each of the following elements: (1) the product was defectively designed so as to render it unreasonably dangerous, (2) a safer alternative design existed, and (3) the defect was a producing cause of the plaintiff’s injuries.” *Garrick v. Autoliv ASP, Inc.*, No. 14-17-00818-CV, 2018 WL 338159, at \*4 (Tex. App.—Houston [14th Dist.] July 12, 2018, pet. denied) (citing *Timpte Indus., Inc. v. Gish*, 286 S.W.3d 306, 311 (Tex. 2009)).

Boston Scientific argues that Carpenter has failed to set forth allegations in her Petition to support a design defect claim because she failed “to describe how the design of the Boston Scientific product was defective,” and her allegation that suitable alternative designs existed was a “naked assertion[] devoid of further factual enhancement.” Def.’s Mot. to Dismiss, Doc. 6 at 6 (quoting *Twombly*, 550 U.S. at 557) (internal quotation marks omitted).

In response, Plaintiff states that, with respect to the first element, she set forth sufficient allegations that the product was defectively designed because “[t]he mesh is designed to stay in place and hold human body parts in place,” and the Advantage Fit “eroded into Plaintiff’s bladder and caused mesh stones and lesions, as well as several removal surgeries.” Pl.’s Resp. (citing Pl.’s Pet., Doc. 1-3, ¶¶ 7, 33-35). Plaintiff further states that she listed several specific ways that Advantage Fit’s design was defective, including biomechanical issues with the design of the mesh, the use of polypropylene material, and the implantation of the Advantage Fit through transvaginal means, which is “an area of the body with high levels of pathogens.” Pl.’s Resp., Doc. 10 at 7;

Pl.’s Pet., Doc. 1-3, ¶¶ 12(a)-(h). The court determines that these allegations are sufficient to plead that the Advantage Fit contained a design defect.

With respect to the second element, Plaintiff responds with a conclusory statement that “[f]easible and suitable alternative designs as well as suitable alternative procedures and instruments” existed “to treat Plaintiff’s condition” at the time she was implanted with the Advantage Fit. Pl.’s Resp., Doc. 10 at 7-8 (quoting Pl.’s Pet., Doc. 1-3, ¶ 21). The court agrees with Defendant that this allegation is a formulaic recitation of the second element for a design defect claim and that Plaintiff has accordingly failed to set forth sufficient factual allegations that “a safer alternative design existed,” as required to plead this claim.

### **3. Strict Liability – Manufacturing Defect**

“Under Texas law, a plaintiff has a manufacturing defect claim when a finished product deviates, in terms of its construction or quality, from the specifications or planned output in a manner that renders it unreasonable dangerous.” *Am. Tobacco Co., Inc. v. Grinnel*, 951 S.W.2d 420, 433 (Tex. 1997). “A plaintiff must prove that the product was defective when it left the hands of the manufacturer and that the defect was a producing cause of the plaintiff’s injuries.” *iLight Techs. Inc. v. Clutch City Sports & Entm’t, L.P.*, 414 S.W.3d 842, 846 (Tex. App.—Houston [1st Dist.] 2013, pet. denied).

Defendant argues that Carpenter failed to state a claim for strict liability based on a manufacturing defect because the Petition “makes no showing that the manufacture of any Boston Scientific product deviated in any respect from the product’s design specifications and makes no showing about how the allegedly-defective manufacture of any Boston Scientific product caused her alleged injuries.” Def.’s Mot. to Dismiss, Doc. 6 at 7. In response, Plaintiff argues that she has pleaded sufficient facts for a manufacturing defect claim based on the allegation that the

manufacturing process “creates a toxic substance” and that the device contained that defect when it left Boston Scientific’s possession. *Id.* (citing Pl.’s Pet., Doc. 1-3, ¶ 12(g)).

Plaintiff’s allegation that she was implanted with an Advantage Fit containing a manufacturing defect does not adequately meet the pleading standard with respect to this claim. In her Response, Carpenter argues that her claim is based on an allegation that “the welding of the mesh itself during production . . . creates a toxic substance that contributes to the degradation of the mesh and host tissue.” Pl.’s Pet., Doc. 1-3 at 6, ¶ 12(h)). This allegation, on its face, appears to relate to the overall design of the Advantage Fit as it pertains to all devices manufactured—not the specific one that Carpenter received—and, therefore, appears to support her design defect claim. Carpenter has not set forth allegations that the alleged toxic substance deviated from the specifications for the Advantage Fit and resulted in a manufacturing defect in the specific device with which she was surgically implanted. The Petition, moreover, in pleading the manufacturing defect claim, makes formulaic and conclusory recitations that the Advantage Fit was “unreasonably dangerous,” but makes no mention of the requisite element that a plaintiff show the device deviated from the specifications or planned output, and how such deviations rendered Plaintiff’s device unreasonably dangerous. As Carpenter has failed to allege that the Advantage Fit deviated from specific specifications or planned output, the court determines that Carpenter has failed to set forth adequate allegations to support her strict liability manufacturing claim.

#### **4. Strict Liability – Failure to Warn**

A marketing defect based on a defendant’s failure to warn is proved “when the evidence shows that a defendant fails to warn of a product’s potential dangers, when warnings are required, and that the lack of adequate warnings or instructions renders an otherwise adequate product unreasonably dangerous.” *Ranger Conveying & Supply Co. v. Davis*, 254 S.W.3d 471, 480 (Tex.

App.—Houston [1st Dist.] 2007, pet. denied); *see also Am. Tobacco*, 951 S.W.2d at 426. The elements of a marketing defect cause of action are: (1) “a risk of harm must exist that is inherent in the product or that may arise from the intended or reasonably anticipated use of the product”; (2) “the supplier of the product knows or reasonably should foresee the risk of harm at the time the product is marketed”; (3) “the product has a marketing defect”; (4) “the lack of instructions or warnings renders the product unreasonably dangerous to the ultimate user or consumer of the product”; and (5) “the failure to warn or instruct causes the user’s injury.” *Ranger Conveying & Supply Co.*, 254 S.W.3d at 480 (citing *Olympic Arms, Inc. v. Green*, 176 S.W.3d 567, 578 (Tex. App.—Houston [1st Dist.] 2004, no pet.)).

Boston Scientific argues that the court should dismiss Carpenter’s claim because she “failed to identify any specific marketing representation or warning about any Boston Scientific product that was seen or received by Plaintiff or her physician.” Def.’s Mot. to Dismiss, Doc. 6 at 7. Boston Scientific further argues that Carpenter has not alleged how any existing warnings were inadequate or how the inadequacy of the warnings is proximately related to her injuries. *Id.* at 7-8. Boston Scientific also argues that under Texas law, Carpenter did not correctly plead her claim because, in this case, the “learned intermediary” doctrine applies, which provides that a manufacturer only has a duty to warn the prescribing physician and not the patient directly. *Id.* at 8. Defendant argues that, pursuant to this doctrine, Carpenter “failed to allege what warnings the implanting physician received regarding the Advantage Fit” and why such warnings were inadequate or the proximate cause of her injuries. *Id.*

In response, Carpenter makes conclusory statements that she pleaded sufficient facts for her failure-to-warn claim based on the factual allegation that Defendant “failed to provide sufficient warnings and instructions . . . [regarding] the dangers and adverse effects” of the



Advantage Fit. Pl.'s Resp., Doc. 10 at 9 (quoting Pl.'s Pet., Doc. 1-3, ¶ 30). Carpenter does not address Boston Scientific's argument that the "learned intermediary" doctrine applies to her failure-to-warn claim.

After reviewing the relevant authority and this court's previous position regarding the applicability of the "learned intermediary" doctrine to claims involving surgical implants, the court determines that the doctrine applies in this case. As correctly noted by Defendant, "Texas recognizes the learned intermediary doctrine, under which manufacturers need only warn the ultimate user's physician." *Dyer v. Danek Medical, Inc.*, 115 F. Supp. 2d 732, 740 (N.D. Tex. 2000) (J. Lindsay) (citing *Baxter Healthcare Corp.*, 965 S.W.2d 656, 662 (Tex. App.—Houston [14th Dist.] 1998, no pet.)). "The learned intermediary doctrine applies to all causes of action, including strict liability, based on a failure to warn." *Id.* (citing *In re Norplant Contraceptive Products Liability Litigation*, 955 F. Supp. 700, 709 (E.D. Tex. 1997), *aff'd*, 165 F.3d 374 (5th Cir. 1999); *Wyeth-Ayerst Labs. Co. v. Medrano*, 28 S.W.3d 87, 94 (Tex. App.—Texarkana 2000, no pet.)). When the doctrine applies, a plaintiff must show that the inadequate warning was the producing cause of his or her injuries. *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 170 (Tex. 2012) (citations omitted). "[W]hen the prescribing physician is aware of the product's risks and decides to use it anyway, any inadequacy of the product's warning, as a matter of law, is not the producing cause of the patient's injuries." *Id.*

This court has previously noted that, although the "learned intermediary" doctrine was originally applied to prescription drugs, Texas courts have extended the doctrine to medical devices. *Dyer*, 115 F. Supp. 2d at 740 (citations omitted). In determining whether the doctrine applies to a specific medical device, this court has identified the following factors justifying the "learned intermediary" doctrine: "the existence of a physician-patient relationship; the physician's

integral involvement in selecting the product; and the physician's superior understanding of the interplay between the product's dangers and the patient's conditions." *Id.* (citing *Bean v. Baxter Healthcare Corp.*, 965 S.W.2d 656, 663 (Tex. App.—Houston [14th Dist.] 1998, no pet.)). While the Texas Supreme Court has not decided the applicability of the doctrine to a personal injury action involving a transvaginal surgical mesh device, some courts in other districts have applied the doctrine to mesh-based surgical implants similar to the Advantage Fit. *See, e.g., Karnes v. C.R. Bard, Inc.*, No. 18-CV-931-WMC, 2019 WL 1639807, at \*7 (W.D. Wis. Apr. 16, 2019); *Runner v. Bard*, 108 F. Supp. 3d 261, 271-72 (E.D. Pa. 2015); *Sanchez v. Boston Scientific Corp.*, 38 F. Supp. 3d 727, 732-735 (S.D. W. Va. 2014); *Tyree v. Boston Scientific Corp.*, 38 F. Supp. 3d 826, 833 (S.D. W. Va. 2014). One Texas court, deciding whether an implanted contraceptive device was subject to the "learned intermediary" doctrine, determined that the doctrine applied because the patient could not receive the device without a prescription and, therefore, the device could only reach the patient by way of a learned intermediary. *Wyeth-Ayerst Labs. Co.*, 28 S.W.3d at 92.

The court determines that, in light of the authority under both Texas law and in other circuits, the allegations in Carpenter's Petition set forth that the Advantage Fit is marketed to physicians and then prescribed to patients pursuant to a physician-patient relationship, whereby the physician has a superior understanding regarding the product's dangers and, therefore, the "learned intermediary" doctrine is applicable to this case. *See Bean*, 965 S.W.2d at 663. Carpenter alleges that the Advantage Fit is "specifically promoted to physicians and patients as an innovative, minimally invasive procedure with minimal local tissue reactions, minimal tissue trauma, and minimal pain while correcting urinary incontinence." Pl.'s Pet., Doc. 1-3 at 5, ¶ 7. Carpenter alleges that Boston Scientific "marketed and sold the Advantage Fit through carefully planned,

multifaceted marketing campaigns and strategies,” which “include, but are not limited to, aggressive marketing and the provision of valuable cash and non-cash benefits to healthcare providers.” *Id.*, ¶ 11. Carpenter alleges that Boston Scientific “provided incomplete, insufficient, and misleading training and information to physicians to increase the number of physicians utilizing the Advantage Fit, and thus increase the sales of these products.” *Id.* at 9, ¶ 23. In pleading her failure-to-warn claim, she alleges that the Advantage Fit was “used in a way reasonably foreseeable to [Defendant] . . . particularly given the educational material or instruction given to physicians in regard to these products.” *Id.* at 13, ¶ 56. These allegations demonstrate that the “learned intermediary” doctrine is appropriate in this case, and, accordingly, Plaintiff’s failure-to-warn claim is limited to the adequacy of the warnings provided to the treating physicians who prescribed and surgically implanted the Advantage Fit.

Plaintiff’s pleadings, as Defendant argues, lack sufficiently specific allegations regarding the warnings provided to the prescribing physicians at Texas Health Presbyterian Hospital Plano regarding the Advantage Fit and the basis for the warnings being inadequate as to render the surgical implant unreasonably dangerous. Carpenter, accordingly, has not met the pleading standard with respect to her failure-to-warn claim, which is subject to Texas’s “learned intermediary” doctrine for the reasons set forth in this section.

### **C. Amendment of Pleadings**

In Plaintiff’s response, she seeks leave of the court to file an amended complaint to allow her to adequately plead her claims in the event the court finds them factually deficient. The decision to allow amendment of a party’s pleadings pursuant to Rule 15(a)(2) of the Federal Rule of Civil Procedure is within the sound discretion of the court. *Foman v. Davis*, 371 U.S. 178, 182 (1962); *Norman v. Apache Corp.*, 19 F.3d 1017, 1021 (5th Cir. 1994) (citation omitted). In

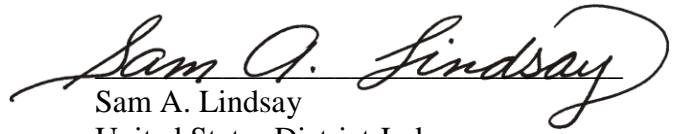
determining whether the allow an amendment of the pleadings, a court considers the following: “undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, [and] futility of amendment.” *Foman*, 371 U.S. at 182; *Schiller v. Physicians Res. Grp. Inc.*, 342 F.3d 563, 566 (5th Cir. 2003) (citation omitted).

In this case, Carpenter has not previously amended her pleadings, and the court does not believe an amendment would be futile or that her request is made in bad faith. Further, the court does not believe that Boston Scientific will be unduly prejudiced, as no scheduling order has been issued in this case. The court, therefore, **grants** Boston Scientific’s motion to dismiss Carpenter’s negligence and strict liability claims but **grants** Carpenter’s request for leave to amend her pleadings to correct the factual deficiencies in accordance with the court’s observations herein set forth.

#### **IV. Conclusion**

For the reasons herein stated, the court **grants** Defendant’s Motion to Dismiss for Failure to State a Claim (Doc. 5); **dismisses with prejudice** Plaintiff’s breach of implied and express warranty claims as being barred by the statute of limitations; and **dismisses without prejudice** Plaintiff’s negligence and strict liability claims but allows her to file an amended pleading regarding these claims consistent with the court’s instructions. Carpenter shall file her amended pleading by **August 7, 2019**. Failure of Plaintiff to file an amended pleading in accordance with the court’s instructions will result in dismissal of this action with prejudice for failure to state a claim upon which relief may be granted pursuant to Rule 12(b)(6), or dismissal under Federal Rule of Civil Procedure 41(b) for failure to prosecute or comply with a court order.

**It is so ordered** this 24th day of July, 2019.

  
Sam A. Lindsay  
United States District Judge